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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,654	03/29/2001	Kenichi Hosoya	10939/2012	6149

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EXAMINER	
PAPPU, SITA S	

ART UNIT	PAPER NUMBER
1636	14

DATE MAILED: 05/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/821,654	HOSOYA ET AL.	
	Examiner	Art Unit	
	Sita Pappu	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/24/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-14 are pending in the instant application. This Office Action is in response to the Amendment filed by the Applicant in paper # 13 on 04/24/2002. Claims 1-14 are under consideration.

Response to the amendment

Claims 1, 3, 5-7, 9-11, 13-14 are amended. Currently, claims 1-14 are under consideration.

The amendments made to the specification have been entered.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Amended abstract has been entered.

The rejection of claims 4, 8, 12 under 35 U.S.C. 112, first paragraph, for lack of affidavit or declaration regarding the biological deposits has been withdrawn in light of Applicant's amendment and provision of English translations.

The rejections of claims 1-6, 7-10, 11-14 under 35 U.S.C. 102(a), have been withdrawn in light of amendment and the priority papers filed.

The rejections of claims 1-6, under 35 U.S.C. 102(b), has been withdrawn in light of amendment and the priority papers filed.

Claims 1, 3, 6, 11 and 14 stand rejected and claims 2, 4, 12, are rejected under 35 U.S.C. 102(b) for reasons of record and the response to arguments, herein, below.

Claims 1-3, 6-7, 10-11 and 14 stand rejected and claims 4, 5, 8, 9, 12, 13 are rejected under 35 U.S.C. 103(a) for reasons of record and the response to arguments, herein, below.

Response to Arguments

In response to the rejection of claims 1, 3, 6, 11 and 14 under 35 U.S.C. 102(b), Applicant argues (page 14, paragraphs 2-4) that Greenwood et al. do not teach transport of substances such as drugs into the cells, nor that the cells exhibit an inside-outside polarity when cultured in vitro paragraph 2) and that the cells are not temperature sensitive (paragraph 3) and amended the claims to recite these properties.

These arguments have been considered but are not found persuasive and claims 1, 3, 6, 11 and 14 stand rejected and claims 2, 4, 12, are rejected under 35 U.S.C. 102(b) as being anticipated by Greenwood et al. (1996; Journal of Neuroimmunology, vol. 71, pp 51-63) for reasons of record and as discussed below.

As conveyed in the rejection made in the previous Office Action (Paper # 10, mailed 01/02/2002), the properties recited above: the transport of substances such as drugs into the cells, inside-outside polarity of cells when cultured in vitro and the temperature sensitivity are all inherent properties of the cells disclosed by Greenwood et al. The claiming of a new use, new function, or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best* 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP 2112.

Further, Greenwood et al. state that their cells could be used as a means of delivering therapeutic genes (page 63, left column, second paragraph) and that the

advantage of their cells is that the SV40 large T-antigen contains the temperature sensitive mutation, tsa58, which results in the large T-antigen being degraded when cells are cultured at temperatures over 37.5 C (page 63, left column, first paragraph), which meets the conditional immortality limitation of the instant claims, as amended.

The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of the evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989).

Thus, Greenwood et al. anticipate the invention claimed in 1-4, 6, 11, 12 and 14.

In response to the rejection of claims 1-3, 6-7, 10-11, 14 under 35 U.S.C. 103, Applicant argues the rejection of record by presenting a piecemeal analysis of the references and their alleged failure to teach the claimed invention.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combination of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues (page 15, paragraphs 2-4) that Rudland et al. do not teach any of the immortalized cells of the instant invention (page 15, paragraph 3). Applicant further states that Rudlland et al. teach cell lines derived from mammary glands and neuronal cells of brain.

Regarding the Greenwood et al. (1998) reference, Applicant argues that the reference does not state that the cells disclosed have the same properties or gene expression as the instant cells and that Greenwood et al. (1998) do not teach that the retinal capillary endothelial and brain capillary endothelial cells are identical in structure (bridging paragraph, pages 15 and 16). Applicant further presents a piece-meal analysis of the references (page 17) and argues that there is no motivation to combine the references and states that their enabled claims cannot be rendered obvious by the references used (page 18) because their claims are directed to different (emphasis in original) immortalized cells, and that Roux et al. and Villalobos et al. do not suggest the establishment of immortalized cells for drug screening. However, the stated motivation for combining the teachings of the references is the teachings by Rudland et al. who teach that their invention is amenable to use in other tissues to generate conditionally immortal cell lines and the teachings by Greenwood et al. (1998) who teach the structural identity of these cell types and teach that they serve as models for studying the blood/central nervous system interfaces. Applicants have not addressed the stated motivation.

These arguments have been considered but are not found persuasive and claims 1-3, 6-7, 10-11 and 14 stand rejected and claims 4, 5, 8, 9, 12, 13 are rejected under 35 U.S.C. 103(a) for reasons of record and as discussed below.

As set forth in the previous office action (Paper # 10, mailed 01/02/2002), Rudland et al. teach that their invention is amenable to use in other tissues to generate conditionally immortal cell lines from transgenic animals expressing the SV40 temperature-sensitive mutant large T antigen mutant tsA58 gene, using proteases. The motivation to use the cells of retinal capillary endothelium and brain capillary endothelium was provided by Greenwood et al. (1998) who teach the structural identity of these cell types and teach that they serve as models for studying the blood/central nervous system interfaces. It is particularly noted that the Applicants themselves agree that the retinal capillary endothelial cells are part of retinal vascular endothelium and that brain capillary endothelial cells are part of cerebral endothelium (page 16, first paragraph). Regarding the use of choroid plexus epithelial cells, the previous office action establishes the motivation provided by Greenwood et al. (1998) who teach that their immortalized retinal pigmentary epithelial cells are similar to the choroid plexus epithelial cells (column 1, lines 24-29).

The expectation of success comes from both Rudland et al. who teaches that their method is amenable to use in other tissues to generate conditionally immortal cell lines and from Greenwood et al. who successfully teach the generation of conditionally immortalized cells from retinal capillary endothelium and teach the structural similarity between their cell types and those used in the instant case. It would be obvious for one

of ordinary skill in the art to use the structurally similar cell types disclosed by Greenwood et al. and be motivated to generate conditionally immortalized cell lines using the method of Rudland et al. It would have been obvious to one of ordinary skill in the art at the time of the invention, to combine the teachings of Greenwood et al. and Rudland et al. to generate conditionally immortalized cell lines from retinal capillary endothelial cells, choroid plexus epithelial cells and brain capillary endothelial cells. The invention, as a whole, is therefore, prima facie obvious.

There is no indication in the specification that the cells of the instant application are any different in function from those described in the art and thus, the Applicants' amendment fails to render the instant invention unobvious over the cited prior art. It still remains that Applicant has not demonstrated a patentable difference between the cells of the instant application and those of prior art. Thus, absent unexpected results, which Applicant fails to provide, one of ordinary skill in the art would have been obviously motivated and would have had an expectation of success to generate conditionally immortalized cell lines of retinal capillary endothelial, choroid plexus epithelial and brain capillary endothelial origin taking advantage of art-recognized properties of the elements and/or cells.

It is obvious to combine known elements and methods for their recognized and known properties. Thus, the invention, as a whole would have been prima facie obvious to one of ordinary skill in the art.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (8:30 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305 1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308 4242 for regular communications and (703) 872 9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

Anne-Marie Baker

ANNE-MARIE BAKER
PATENT EXAMINER

S. Pappu
May 17, 2002